IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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PFIZER INC. and UCB PHARMA GMBH, Plaintiffs, v. ALKEM LABORATORIES LTD., et al., Defendants.	)	Civil Action
	)	NO. 13-1110(GMS)
	)	CONSOLIDATED

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Wilmington, Delaware
Tuesday, November 18, 2014
9:30 a.m.
Markman Hearing

- - -

BEFORE: HONORABLE GREGORY M. SLEET, U.S.D.C.J.

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:22:24
:33:40

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:33:40 **THE COURT: Good morning. Please, take your**
:33:42 **seats.**
:33:43 **We have only one term. Right?**
:33:46 **MR. BLUMENFELD: Correct, Your Honor.**
:33:48 **THE COURT: Mr. Blumenfeld.**
:33:53 **MR. BLUMENFELD: Good morning, Your Honor. Jack**
:34:03 **Blumenfeld from Morris Nichols for Pfizer and UCB. Along**
:34:07 **with me at counsel table, James Trainor, Ryan Johnson, Bob**
:34:15 **Counihan, and Jeffrey Oelke, all from White & Case. Mr.**
:34:17 **Trainor will be doing the plaintiffs' presentation this**
:34:19 **morning, with Your Honor's permission.**
:34:22 **Sitting in the back of the courtroom in the**
:34:25 **second row is Stephane Drouin and Jurgen Hassa, who are here**
:34:30 **from UCB. In the row behind them, Chase Romick, who is with**
:34:35 **Pfizer.**
:34:39 **THE COURT: Thank you, Mr. Blumenfeld.**
:34:39 **Ms. Farnan.**
:34:39 **MS. FARNAN: Good morning, Your Honor. Kelly**
:34:41 **Farnan from Richards, Layton & Finger on behalf of the**
:34:44 **defendants Accord and Alkem. I am joined by my co-counsel**
:34:47 **from Sughrue Mion Michael Dzwonczyk. Mr. Dzwonczyk is going**
:34:51 **to make the presentation on behalf of the plaintiffs today.**
:34:54 **Also on behalf of Accord and Alkem from Sughrue Mion is**
:34:58 **Chandran Iyer.**
:35:00 **THE COURT: Good morning.**

Do any other defendants want to be on the record?

MR. MOORE: Good morning, Your Honor. David Moore from Potter Anderson representing Apotex. From Rakoczy Molino is Kevin Burke.

THE COURT: Good morning.

Mr. Phillips.

MR. PHILLIPS: Good morning, Your Honor. Jack Phillips on behalf of Lupin. With me in the back of the courtroom is Jamaica Szeliga from the Leydig firm in Washington, D.C.

MR. POFF: Good morning, Your Honor. Adam Poff on behalf of Sandoz. With me is Kristen Venegas from McDermott Will & Emery. And from Sandoz, Brian Hurst.

THE COURT: Good morning, counsel.

MR. GATTUSO: Good morning, Your Honor. Dominick Gattuso from Proctor Heyman. I have with me Mr. Steve Moore from Kelley Drye on behalf of Zydus Pharmaceuticals.

THE COURT: Good morning, counsel.

MR. SCHLADWEILER: Good morning, Your Honor. Ben Schladweiler from Seitz Ross on behalf of Wockhardt.

THE COURT: Good morning, counsel.

MR. CASTELLANO: Good morning, Your Honor. Jeffrey Castellano from Shaw Keller on behalf of Alkem.

:35:59 **MR. ATHEY: Good morning, Your Honor. Clayton**
:36:02 **Athey from Prickett, Jones & Elliott on behalf of Amerigen.**
:36:04 **With me today is William Hare of McNeely, Hare & War. Also**
:36:09 **Gabriela Materassi.**
:36:17 **MR. SEAMAN: Good morning, Your Honor. John**
:36:18 **Seaman from Abrams & Bayliss on behalf of Hetero. With me**
:36:22 **from Axinn, Veltrop & Harkrider LLP is my colleague, Chad**
:36:28 **Landmon.**
:40:01 **THE COURT: Good morning.**
:40:02 **There is not much to talk about. Just one term.**
:40:07 **So, plaintiffs, what are you doing?**
:40:09 **MR. TRAINOR: Your Honor, I have some copies of**
:40:10 **our slides. If I may approach?**
:40:13 **THE COURT: Yes, please.**
:40:32 **MR. TRAINOR: Good morning, Your Honor. James**
:40:40 **Trainor of White & Case on behalf of the plaintiffs, Pfizer,**
:40:44 **Inc. and Alkem Labs, Ltd.**
:40:50 **Your Honor, this is a Hatch-Waxman patent**
:40:54 **infringement case against ten defendants presently. Our**
:40:56 **understanding is two of the defendants, Hetero and Hetero**
:41:00 **Labs, do not join in the dispute that is before the Court**
:41:04 **this morning.**
:41:06 **Your Honor, there are five patents in this**
:41:09 **lawsuit. Four of those patents are not at issue today.**
:41:12 **Those four patents, which we have previously referred to in**

:41:18 **the proceedings of this case as the compound patents, are**
:41:20 **shown on the top of the slide there. The patent at issue**
:41:24 **today is the '650 patent, or what we refer to as the salt**
:41:27 **patent. That is shown at the bottom of the slide there.**
:41:32 **One important thing to know about the**
:41:33 **relationship between the patents in suit, the four compound**
:41:37 **patents at the top of the slide are in the same patent**
:41:40 **family. That is, they are related, they claim priority**
:41:43 **through common priority applications.**
:41:46 **The '650 patent is not related to the compound**
:41:50 **patents. However -- and this is quite important -- the**
:41:55 **compound patents are not prior art to the '650 patent. That**
:42:00 **is contrary to the statements repeatedly in the defendants'**
:42:04 **briefing that there is prior art, prior art applications to**
:42:09 **the '650 salt patent, which is a priority application to the**
:42:13 **compound patents.**
:42:16 **So the reason why it is not prior art -- it is a**
:42:18 **little bit involved -- but it's clear that under no section**
:42:22 **of 102 do the compound patents or any of the priority**
:42:25 **documents qualify as prior art. The defendants cite no**
:42:30 **legal basis to the contrary.**
:42:33 **Very briefly some background, for pertinent**
:42:36 **context in the dispute here about the '650 patent.**
:42:40 **The '650 patent is entitled Stable Salts of**
:42:48 **Novel Derivatives of 3,3-Diphenylpropylamines.**

:42:48 **3,3-diphenylpropylamines are the general class of compounds.**
:42:52 **And specifically claimed in Claim 1 is a subgenus of those**
:42:57 **diphenylpropylamines that are referred to as phenolic**
:43:04 **monoesters. Formula I of Claim 1 are various salts of the**
:43:07 **genus of phenolic monoesters from the patent.**
:43:12 **As you can see, Claim 1 is a traditional,**
:43:15 **straightforward chemical compound claim and nothing more.**
:43:18 **This claim is defined entirely by chemical structure, and we**
:43:23 **submit is unambiguous to a person of ordinary skill in the**
:43:26 **art, whether that is organic chemistry, salt chemistry, or**
:43:29 **what have you.**
:43:33 **There are also 24 claims in the '650 patent.**
:43:36 **Nine are asserted against the defendants presently, although**
:43:39 **we are in the process of trying to narrow that number. Of**
:43:42 **course, again, only one is at issue today.**
:43:46 **The '650 patent begins, from its outset,**
:43:51 **explaining that there are three inventions in this patent.**
:43:56 **Right in Column 1 it states that the inventions are salt**
:44:00 **compounds themselves, separately a method for manufacturing**
:44:04 **those salt compounds, and additionally a method for**
:44:07 **manufacturing intermediate compounds which are used along**
:44:11 **the way in the synthesis process that may ultimately lead to**
:44:14 **the salt.**
:44:15 **I should note that a species of the Claim 1**
:44:19 **compounds is the sodium phenol monoester salt fesoterodine**

:44:26 **fumarate. That is the active pharmaceutical ingredient of**
:44:29 **the accused product in this case.**
:44:37 **Very briefly, Your Honor, of these three**
:44:40 **inventions, salts are the key invention here. In the course**
:44:43 **of the development of what became the accused product in**
:44:47 **this case, what the inventors observed was that the**
:44:49 **free-base form of this genus of compounds exhibited less**
:44:56 **than ideal stability and it made it less than an ideal**
:44:59 **candidate as a practical drug candidate. A solution to**
:45:03 **that, if it could be done, was to try to convert those**
:45:06 **compounds to salt forms so they could be more available for**
:45:09 **use in a pharmaceutical application.**
:45:12 **Once the inventors discovered that, they also**
:45:15 **discovered separately a method for manufacturing those**
:45:18 **salts, and specifically, and separately, a method for**
:45:22 **manufacturing the particular intermediate products, and**
:45:24 **particularly, the particular intermediate that we refer to**
:45:29 **as the free base, or the base compound, which is essentially**
:45:33 **the starting materially for making the salt. Due to some**
:45:39 **efficiencies in the manufacturing process, the process as**
:45:42 **disclosed here in the defendants' '650 patent, that renders**
:45:45 **a good yield of pure sodium compounds and free-base**
:45:50 **compounds that enable the manufacturer to make the drug.**
:45:53 **Once again, three separate inventions: the salts**
:45:57 **themselves, a method for manufacturing them, and an**

:45:59 1 **intermediate product, all separately disclosed, all**
:45:59 2 **separately claimed.**
:46:07 3 **This slide shows representative claims in the**
:46:10 4 **patent to these delineated inventions. Claim 1 is**
:46:15 5 **representative of the compounds claims, the claims to the**
:46:17 6 **salt compounds themselves. Of course, Claim 1 is the claim**
:46:21 7 **in dispute today. Separately, in the middle, you have Claim**
:46:24 8 **7. Claim 7 is an independent claim to a method of**
:46:30 9 **manufacturing the salts of Formula I. That is, Claim 7 is a**
:46:33 10 **method of manufacturing the compounds of Claim 1.**
:46:37 11 **On the right-hand side, we have Claim 18. Claim**
:46:41 12 **18, also an independent claim. Claim 18 relates to the**
:46:45 13 **separate third invention, the method of manufacturing the**
:46:47 14 **intermediate compounds. What is depicted there is a**
:46:51 15 **free-base form of the ultimate intermediate compound prior**
:46:55 16 **to making the salt. That is Claim 18.**
:46:58 17 **So three sets of claims directed to three**
:47:00 18 **different inventions.**
:47:06 19 **Turning now to the parties' competing**
:47:09 20 **constructions of Claim 1, on the left side of the slide you**
:47:12 21 **have Claim 1 as it issued. As Your Honor knows, the**
:47:15 22 **plaintiffs submit this claim is entitled to its plain and**
:47:17 23 **ordinary meaning. As I said before, this is a**
:47:19 24 **straightforward chemical compound. The only language in**
:47:23 25 **this compound comprises chemical structure. And the only**

limitations are chemical structures that can be substituted at the R and X positions of the formula. There is nothing ambiguous about this claim.

By contrast, on the right, we have defendants' construction. Even to the untrained eye, we can see that that construction looks nothing like Claim 1 as it issued and as it would be viewed by the public, where we have to evaluate whether or not they infringe.

Even the depicted structure, the depicted molecule used in the defendants' construction is quite different from the molecule in Claim 1 as it issued. That particular molecule is actually a different intermediate product, lead products upstream from the ultimate salt that's claimed in Claim 1.

A reading of the defendants' construction, it should be noted, does not result in a salt. So the intent of the inventors with Claim 1, as is shown in the title of the patent, as shown in the disclosure, consistent with the chemistry, is to claim a salt. Defendants' construction doesn't even lead one to a salt.

A few other notes about defendants' proposed construction here on the right, Your Honor, it really sort of undermines the credibility of their position. First of all, unlike your traditional claim construction case, the defendants are not trying to single out a phrase or

:48:50 **particular claim term of Claim 1 and propose a construction**
:48:55 **for it. Instead, they have rewritten the claim in its**
:48:59 **entirety. There is no support cited by defendants for a**
:49:02 **construction of this nature. That is a complete rewrite of**
:49:06 **the claim.**
:49:07 **In addition, you will notice at the top that**
:49:09 **this construction proposed by the defendants is not really**
:49:12 **tied to Claim 1. It is a proposed construction for Claim 1,**
:49:16 **but it suggests that this governs all the claims that are**
:49:20 **disclosed in the '650 patent. This is unconventional, to**
:49:24 **say the least. And certainly the defendants don't cite any**
:49:27 **support for a construction of that nature.**
:49:30 **And finally and most importantly, at the crux of**
:49:32 **this matter, the use of the words "those obtained by" in**
:49:36 **defendants' proposed construction signal pretty clearly that**
:49:39 **the defendants intend to convert a straightforward chemical**
:49:42 **compound claim into an entirely different type of claim, and**
:49:47 **that is a product-by-process claim.**
:49:58 **The issue before the Court today, as it has been**
:50:01 **framed by the defendants, is whether the inventor of the**
:50:04 **'650 patent disavowed compounds made by any process other**
:50:10 **than the process that they import into their construction,**
:50:13 **and which is a process described in the '650 patent. That**
:50:19 **is a process that they repeatedly referred to as the**
:50:22 **"special reaction" process or the "crucial" process.**

:50:25 **The proposal is that the inventor disavowed any**
:50:29 **other process, as we understand it.**
:50:31 **In fact, the relief that is sought here is**
:50:33 **really extreme, because it's more than just a disavowal**
:50:37 **case. What the defendants need to overcome or what they**
:50:42 **invoke here are actually three separate exceptions that are**
:50:45 **well settled under the law of claim construction. They are**
:50:49 **each separately treated in the law. They each are not**
:50:52 **easily overcome.**
:50:53 **The first is the general prohibition on**
:50:56 **importing limitations into the claim, which, as Your Honor**
:50:59 **has probably heard many times, is one of the cardinal sins**
:51:03 **of claim construction. That is generally what needs to be**
:51:05 **accomplished here.**
:51:06 **Separate from that, as we just discussed, the**
:51:10 **defendants invoke the very rare support for converting a**
:51:17 **product claim into a product-by-process claim. That is**
:51:21 **separately treated. That is sort of a separate analysis**
:51:24 **from the disavowal itself.**
:51:26 **So in this case, the defendants first have to**
:51:29 **justify importing a limitation into the claim; then they**
:51:32 **have to suggest that the claim language clearly triggers an**
:51:37 **indication that the claim, while not written as a process**
:51:41 **claim, should be treated as a process claim; and then the**
:51:44 **defendants will have to show that even if the claim should**

:51:50 1 **be construed that way, that there was a particular process**
:51:52 2 **that was clearly and manifestly disavowed.**
:51:56 3 **Those are very high hurdles to clear, each of**
:51:59 4 **them, and the defendants clear none of them.**
:52:02 5 **It should be noted with respect to these cases**
:52:04 6 **that talk about converting a product claim to a**
:52:07 7 **product-by-process claim that the purpose of**
:52:11 8 **product-by-process claims -- and this is enunciated by the**
:52:14 9 **Supreme Court in BASF, by the Federal Circuit in Atlantic**
:52:17 10 **Thermoplastics, and this District in the Biacore decision --**
:52:20 11 **product-by-process claims, the purpose of them is really to**
:52:23 12 **define a claim where they otherwise can't be defined, in**
:52:27 13 **other words, where a claim cannot be defined by structure.**
:52:30 14 **That is the polar opposite of the situation**
:52:33 15 **here, where Claim 1 is clearly defined by chemical**
:52:40 16 **structure. There is absolutely no call for treating this**
:52:43 17 **claim as a product-by-process claim.**
:52:45 18 **Put simply, the premise of defendants' argument**
:52:47 19 **is as follows, again, as we understand it: The salt**
:52:50 20 **compounds in the '650 patent have some beneficial**
:52:53 21 **properties. According to the defendants, those salts were**
:52:57 22 **already in the prior art. What they specifically point to**
:53:02 23 **is something referred to as the 212 PCT application. Again,**
:53:06 24 **this is a priority application of the other compounds of the**
:53:10 25 **patent in suit that are not disputed here today. They**

:53:13 **suggested these were prior art and they suggest these salts**
:53:16 **were already in the prior art. Therefore, according to the**
:53:19 **defendants, the only way that the salt claims in the '650**
:53:21 **patent are patentable is if they are limited to this**
:53:24 **process, because if they were disclosed in the prior art**
:53:27 **already, the only way they could justify their validity is**
:53:30 **to limit them to a particular process, which, according to**
:53:33 **the defendants, is the only thing new in the '650 patent.**
:53:41 **Those premises are all resting on a number of**
:53:45 **assumptions, each of which is decidedly false.**
:53:50 **The first thing is that the defendants assume**
:53:53 **that, in fact, there was an inferior process in the prior**
:53:55 **art. What they are suggesting is that the prior processes**
:53:58 **didn't result in the claims of this patent, and therefore**
:54:01 **you are limited to the process that is disclosed in this**
:54:04 **patent.**
:54:05 **In fact, there was no process in the prior art.**
:54:08 **The priority documents to the compound patent, the 212 PCT,**
:54:13 **is not prior art as a matter of law. In addition,**
:54:17 **factually, there is a process disclosed in that 212 PCT**
:54:22 **application that they allege is prior art. And that**
:54:25 **chemistry, that process, is the very same process that's**
:54:27 **disclosed in the '650 patent, which raises the question:**
:54:32 **What exactly are they disavowing? The same process in that**
:54:38 **reference that the defendants point to.**

:54:40 **The defendants' premise also assumes that the properties of the salt, for example, the properties in the patent, the level of purity, the yield, the fact that it's in solid crystalline form, the defendants assume that all those properties are impacted by the process, that they are impacted or influenced by the intermediates that you use to get to the salt. But no person of ordinary skill would ever suggest that that is the case, that the way or method that you get to the ultimate free base has no bearing on what the properties of the salt are.**

:55:12 **In addition, the argument assumes that Claim 1 requires these properties. But it doesn't. If you look at Claim 1, Claim 1 is just simply to the salt. It is not to a salt having certain purity, a salt in solution form, a salt in solid form, a salt giving way to certain yield. None of that is required by the claim.**

:55:34 **The implication is you can't get good salts without using this process. That assumes that the claim requires any of that. And it does not.**

:55:44 **Finally, and critically, the defendants assume that the special reaction process that they repeatedly refer to in their briefing is actually linked to the salt compounds, it is actually linked to the claimed compounds, the claims for the compound themselves.**

:55:57 **That is not the case. A fair reading of the**

:55:59 **specification makes very clear that to the extent that the**
:56:02 **special process is special at all or is linked to anything**
:56:05 **at all, it is linked to the method of manufacturing the**
:56:08 **salts and a method of manufacturing the compounds. Again,**
:56:11 **separately disclosed, separately claimed inventions.**
:56:16 **No case that the defendants cite supports their**
:56:21 **position on claim construction. But they are all very**
:56:24 **instructive because they set forth a very formulaic analysis**
:56:29 **that the courts routinely use when assessing whether**
:56:32 **disavowal has occurred, when assessing whether any product**
:56:36 **claim should be limited to a product-by-process claim.**
:56:39 **That is sort of a sequential review of the**
:56:40 **intrinsic evidence.**
:56:42 **The courts in these cases are looking for**
:56:45 **particular evidence, they are looking for particular facts**
:56:47 **with respect to each segment of the intrinsic evidence. So**
:56:54 **we will cite to intrinsic evidence in turn.**
:56:58 **In contrast, with all of the decisions cited by**
:57:00 **the defendants, the claims here have no language that would**
:57:04 **suggest to the reader that any importation of any limitation**
:57:08 **is required. Certainly, no language that suggests a process**
:57:12 **should be imported, and no language in the claims that**
:57:14 **suggests a disavowal in and of itself.**
:57:18 **Again, Claim 1 is entirely defined by chemical**
:57:22 **structure. There is no other language in the claim other**

than the language of chemistry.

So by contrast, you have these decisions, for example, the Andersen decision, which the defendants rely on heavily in support for the proposition of disavowal. The Andersen claim that was at issue, one of the terms that was in the claim was the term "extrudate." Extrudate is by definition a product by process. Extrudate is some material that is extruded from an extrusion process.

So the courts are looking for that kind of language, language that suggests there is an ambiguity, language that suggests there is something operational or functional about the claim, language that suggests certain properties of the claim are required to achieve or exhibit results. None of that language is present in Claim 1 here.

Courts also look to the other claims of the patent. While Claim 7 is not asserted and no other claim of the '650 patent is at issue here today, it is important to consider that Claim 7 already claims, as we pointed out earlier, a method of manufacturing the very same compound of Claim 1. The defendants by and large ignore this. But what's relevant here is to sort of consider the fact that if you were to adopt defendants' construction, you would have to superimpose it over the claim. That is what claim construction is. I should be able to superimpose that claim construction over Claim 1 as they propose it. If I do that,

:59:02 and sticking to the appropriate law and the proposition
:59:08 under the patent law that claim terms used across the patent
:59:10 are afforded the same meaning, what that means is Claim 7
:59:15 would read, A method of manufacturing compounds of General
:59:19 Formula I, which the defendants have now defined by its
:59:22 method of manufacture.
:59:23 So it would be a method of manufacturing a
:59:26 compound that is manufactured this way by the same
:59:29 manufacturing process. It would be repetitive, superfluous.
:59:32 Claim 7 would read nonsensically.
:59:38 Next, the courts look to the specification, of
:59:41 course. The language is pretty clear. The standard is
:59:45 pretty clear across all the decisions cited by both parties
:59:48 that what the courts are looking for is a manifest, clear,
:59:53 unambiguous, surrender of claim scope. This is seen by
:59:57 expressly exclusionary language somewhere in the
:59:59 specification.
:59:59 The cases cited by defendants hit on a couple of
:00:03 terms that the cases themselves sort of alluded to, when
:00:06 looking for terms like "essential," "applies to all
:00:09 embodiments," cases where the specification talks about "The
:00:13 present invention is" or "This invention is," followed by a
:00:18 limiting property."
:00:19 Probably the main case cited by the defendants
:00:22 in support of a disavowal with respect to the specification

:00:24 **is the X2Y case. In the X2Y case, in determining what kind**
:00:30 **of specification it was, what phrase, the feature was**
:00:33 **universal to all embodiments of the invention.**
:00:38 **Now, the '650 patent contains no such language.**
:00:41 **You can read it and confirm that. It certainly contains**
:00:45 **none of that language with respect to or in connection with**
:00:48 **a special reaction process or a crucial process. In fact,**
:00:53 **the only reference to any phrase remotely resembling those**
:00:57 **cases is the phrase "the present invention" or "the**
:00:59 **invention."**
:01:00 **In Column 2, right up front, the beginning of**
:01:02 **the '650 patent, the inventors uses that phrase, "The**
:01:06 **present invention is," "The present invention is the**
:01:09 **method," "The present invention is the salt," "The present**
:01:12 **invention is a method for providing for a high yield."**
:01:16 **When they are defining the present invention, we**
:01:19 **can see clearly we are talking about the invention as we**
:01:22 **described it before, a broad description of salts, a broad**
:01:25 **description of a method of manufacturing, a broad**
:01:29 **description of a method that provides for a high yield for**
:01:32 **the intermediate products.**
:01:33 **This is broad language signalling the inventor**
:01:38 **had no design on limiting the scope of his patent.**
:01:41 **Certainly, the word "special reaction process" or "crucial**
:01:44 **process" is nowhere near the reference to "the present**

:01:48 **invention" or "the invention."**

:01:53 **Defendants really base their entire argument on**
:01:57 **the reference to this special reaction process. I think it**
:02:00 **appears something like ten times in their briefing. In**
:02:04 **fact, it only appears twice in the patent. Focusing on the**
:02:13 **passage of Column 9 of the patent, the defendants cite this**
:02:15 **passage, "In order to obtain the compounds in accordance**
:02:15 **with the invention in the form of their salts, the special**
:02:21 **reaction process via particular intermediate stages and**
:02:23 **individually identifiable intermediate products is crucial."**
:02:29 **This is the passage defendants cite from Column 9.**

:02:32 **The sentence begins, "In order to obtain." This**
:02:34 **is the same language that is in the defendants'**
:02:37 **construction, which is a construction that proposes limiting**
:02:40 **to a process. "In order to obtain" is signaling, I am about**
:02:44 **to tell you what my support is for my claims to the method**
:02:48 **of manufacturing process. So the special reaction process**
:02:52 **is in reference to a description of that separately claimed**
:02:57 **invention, more particularly, the separately claimed**
:03:00 **invention of the process for manufacturing intermediates and**
:03:04 **the intermediate products.**

:03:06 **That is really a key distinction. These are**
:03:08 **very different molecules. There is no reference here or no**
:03:11 **suggestion that, whatever this process is, it is supposed to**
:03:14 **limit all salts that are covered by the claims of this**

patent.

THE COURT: Counsel, I am looking at that same column. If the process is crucial for obtaining the compounds, couldn't that be construed as a clear disavowal?

MR. TRAINOR: I would suggest not, Your Honor, respectfully, because what is really crucial and special about this process has to do with the solvents that are used in the process and to make that final intermediate. We had that reference in the passage of the third invention, which is about getting a good yield of that starting material. That is what this is in reference to.

Maybe there is some way to read this where you can say, well, this is connected to the salts. But we submit that this and the following description, which is a description of the method of making one species of that compound, which is fesoterodine fumarate, is being described.

The fact that it is crucial and special is quite different than saying it is required or I am excluding all other processes. It is just saying, look, it is important that you do it if you want to get a high yield of these intermediates. It is important that you follow this, because, depending on how you do the synthesis, you might get a lower yield, you might get some salts that are oily in form, you might get some salts that are amorphous. And that

really is of no consequence, because those salts, however impractical they are relative to highly pure crystalline salts, they are still covered by Claim 1. That is still the intellectual property of this inventor.

So I don't think that this is as remarkable as defendants suggest it is.

In addition, Your Honor, what the defendants cut out from that passage in their briefing is the very next sentence. The very next sentence says, "This is explained using Reaction Diagram 1," or Figure 1, on the face of the patent, "in which the conversions with R-configured compounds are described." This is the racemate form of the glycemic, the enantiomer form of the genus of compounds.

But it concludes very clearly, but without this being restrictive, without this being restrictive, this language that is diametrically opposed to language of clear exclusion, of manifest exclusion of the claim scope or disavowal of claim scope, that is not anywhere in the ballpark of an exclusion. And the inventor expressly carved that out.

The only other place where "special reaction process" is referenced in the '650 patent is up front, right at the bottom of Column 1, where the inventor claimed it in the background of the invention. We have highlighted the portions of the specification here and I have blown them up.

:06:05 **At the top, the figure that has been blown up at**
:06:09 **the top of the slide here, that is Formula A. Formula A is**
:06:12 **a reference throughout the patent. What Formula A is, it is**
:06:16 **the free-base form. This is the base compound for making**
:06:20 **the salts. Again, very different compound than the salt**
:06:25 **itself. This compound, there are many observations**
:06:27 **discussed about the stability of this compound. Be that as**
:06:30 **it may, you need this compound to ultimately make the salts.**
:06:34 **So you need to be able to make it and you need to be able to**
:06:37 **make it with relative efficiency.**
:06:40 **That aside, the other reference to special**
:06:43 **reaction process described at the bottom of this column --**
:06:46 **and we can zero in here, it's been blown up --**
:06:49 **"Surprisingly, it has now been found that the**
:06:52 **above-mentioned disadvantages can be avoided if compounds**
:06:54 **with the structure of general Formula A, once they have been**
:06:57 **prepared under a special reaction process, are converted**
:07:01 **with a physiologically compatible inorganic or organic**
:07:04 **acid..."**
:07:05 **So it couldn't be more clear from this passage**
:07:08 **that the inventor is connecting the special reaction process**
:07:12 **to the free base, to the base compound, to the starting**
:07:16 **material, not to the salt. That compound is separately**
:07:19 **claimed, as we saw already. That compound in and of itself**
:07:22 **is an invention. An improved method for making that**

:07:26 **compound is disclosed and disclaimed.**

:07:29 **The reference to special reaction process**
:07:32 **disconnected from the salt is at least not directly**
:07:36 **connected, and specifically refers to the free-base compound**
:07:38 **here, which is not the subject of Claim 1.**

:07:47 **Finally, the courts look to the prosecution**
:07:50 **history if it is in evidence. And very simply, what the**
:07:53 **courts are looking for in these disavowal cases or these**
:07:57 **conversion to product-by-process cases are instances where**
:08:00 **an applicant is distinguishing prior art upon rejection and**
:08:07 **that distinguishing of the prior art is necessarily carving**
:08:11 **out some of the claim scope that the claim might otherwise**
:08:16 **be read to have. That has not occurred in this case, and**
:08:19 **for good reason.**

:08:23 **The prosecution history of Claim 1 is relatively**
:08:28 **uneventful here. This is shown in the slide. There was one**
:08:33 **office action, and there was no rejection of that claim over**
:08:36 **any prior art. In fact, the only rejection that was made**
:08:43 **was a provisional double-patenting rejection over the**
:08:47 **co-pending, co-owned application that the prior art document**
:08:55 **for the compound patents, that is, the U.S. version of that**
:08:59 **212 PCT.**

:09:01 **Far from being prior art and being rejected as**
:09:04 **prior art by the Patent Office, the Patent Office recognized**
:09:07 **that it was not prior art, and therefore made a provisional**

:09:13 **double-patenting rejection which the applicant overcame with**
:09:16 **a terminal disclaimer, and the claim was allowed.**
:09:20 **So every case that the defendants cite has**
:09:25 **facts, in terms of disavowal, they have facts where the**
:09:28 **applicants were distinguishing prior art and the disavowal**
:09:30 **was commensurate with the distinction over the prior art.**
:09:34 **Anderson, Astra, C.R. Bard, SciMed, Verizon, all those cases**
:09:40 **have that fact.**
:09:41 **By contrast, in this case, we never had any**
:09:43 **rejection over the prior art. We therefore never**
:09:46 **distinguished over any prior art, and thus didn't even have**
:09:49 **the occasion to disavow by virtue of some argument to**
:09:53 **distinguish prior art.**
:09:55 **Those facts are not here.**
:10:00 **In summary, Your Honor, there are three**
:10:02 **inventions here, separately disclosed, separately claimed,**
:10:07 **one of which is the salt compounds, and those are the salt**
:10:10 **compounds of Claim 1.**
:10:11 **The intrinsic evidence, as we just went through,**
:10:14 **is completely devoid of any suggestion that there was a**
:10:17 **disavowal or that a conversion to a product-by-process claim**
:10:21 **is appropriate.**
:10:21 **And I just want to reiterate that the fact that**
:10:26 **the defendants' argument rests on a supposed process, the**
:10:32 **salts being disclosed in the prior art, there is no prior**

art. The reference that they allude to in their briefing is not prior art as a matter of law. And that is important, because the Vanguard decision by the Federal Circuit is really on point here when it comes to taking a standard product or compound claim and attempting to convert it to a product by process.

The defendants only distinguish that case by saying, the difference with that case is that those claims, the subject matter of those claims was actually novel. So the implication is these salts are not novel. But, in fact, they are novel, and there is no prior art.

That is all I have, Your Honor. Thank you very much.

THE COURT: Thank you, counsel.

MR. DZWONCZYK: Your Honor, I also have some slides. May I approach?

THE COURT: Yes.

MR. DZWONCZYK: Your Honor, as the plaintiffs --

THE COURT: Counsel, remind of your name.

MR. DZWONCZYK: Mike Dzwonczyk from the Sughrue Mion firm. I am here for Accord and Amneal, but speaking on behalf of all the defendants on the claim terms set forth, except for Hetero and Hetero Labs.

As the plaintiffs state, Your Honor, this case pertains to fesoterodine fumarate. It is a drug to treat

overactive bladder. Before getting right to our claim construction points, I would like to spend a minute or two talking about the background of this patent, what happened before, because I think it will help better understand the defendants' position.

Prior to this patent, a drug called tolterodine was used to treat overactive bladder. It was commercially marketed, patented, and hadn't been discovered. After a patient took tolterodine, it was discovered and reported in the literature that tolterodine was metabolized by a patient to its active form called 5-HMT, 5-hydroxymethyl tolterodine. That means a patient, after taking tolterodine, would actually add the hydroxyl group onto the molecule and form in-vivo the more active form.

But tolterodine had certain drawbacks. The biggest drawback was that certain patients taking tolterodine metabolized tolterodine at different rates.

So in extensive metabolizers, 5-HMT was formed rather quickly, and a high amount of the drug got to the active site, the muscular receptors and bladder. In poor metabolizers, the drug was actually metabolized more slowly, as tolterodine became bound up with plasma proteins. So a smaller amount of the drug would effectively get to the active site.

The problem with the prior art tolterodine was

:13:33 **inter-patient variation. Different patients would actually**
:13:37 **tolerate the drug differently, and depending on what kind of**
:13:41 **metabolizer you were, you actually might get a different**
:13:43 **amount of the active form to the site.**
:13:47 **The challenge became how to get the active form**
:13:50 **5-HMT to the active site of a patient. The most immediate**
:13:54 **solution was to simply administer it directly. I think**
:13:58 **scientists recognized and the literature reported that 5-HMT**
:14:02 **was extremely hydrophilic. It was very water-soluble. As**
:14:06 **such, it couldn't permeate biological membranes very easily.**
:14:12 **It simply would get passed through.**
:14:13 **So the challenge became how to take the active**
:14:17 **metabolite, 5-HMT, and get it to the active site of the**
:14:21 **patient.**
:14:22 **So researchers began working on certain ways to**
:14:26 **do that. And the '650 patent tells us that prodrugs of**
:14:29 **5-HMT were made.**
:14:31 **Prodrugs are precursors, actively metabolized --**
:14:36 **I don't mean to go into that very extensively.**
:14:38 **As a result of that work, a number of prodrugs**
:14:41 **or precursors of 5-HMT were prepared, one of which was**
:14:48 **fesoterodine. What happens after a patient takes**
:14:51 **fesoterodine, which is much more lipophilic than 5-HMT, the**
:14:56 **body essentially cleaves off the isobutyl portion and 5-HMT**
:15:02 **will result.**

:15:06 **Fesoterodine is an ester derivative of 5-HMT.**
:15:09 **It is converted. But to be clear, the prodrugs, including**
:15:13 **fesoterodine, they are not the subject of the '650 patent.**
:15:16 **The plaintiffs tell us it's the salt. And that's where we**
:15:19 **begin our analysis.**
:15:23 **The compounds are called**
:15:24 **3,3-diphenylpropylamines because the core of general Formula**
:15:30 **I is a propyl amine, three carbon units with an amine or an**
:15:34 **NH group on the end. The carbons are numbered, 1, 2, and 3.**
:15:38 **And we see attached to Carbon No. 3 two phenyl groups. And**
:15:42 **that's why these compounds are called**
:15:44 **3,3-diphenylpropylamines. That is what is claimed, this**
:15:48 **general salt structure, in Claim 1, and that is fairly**
:15:51 **straightforward.**
:15:53 **On its face the defendants agree, there is**
:15:55 **nothing unclear about the language of Claim 1. But this is**
:15:59 **claim construction. It's not statutory construction. So we**
:16:02 **have to look at the intrinsic evidence, as Your Honor is**
:16:05 **aware.**
:16:06 **If we look at the very first page of the patent,**
:16:09 **we find the title and abstract. The title tells us we have**
:16:14 **stable salts of novel derivatives of**
:16:16 **3,3-diphenylpropylamines. They are highly pure, they are**
:16:20 **crystalline, et cetera.**
:16:21 **The abstract also tells us that the stable**

:16:25 **crystalline intermediates are essential for obtaining the**
:16:29 **compounds of the invention. Before we even turn the page,**
:16:33 **we are told about the highly stable crystalline nature of**
:16:36 **the claimed compounds and the essential nature of the**
:16:39 **intermediates used to obtain them. Just to make sure we**
:16:42 **understand that, the patentees go on, right in Column 1, and**
:16:46 **tell us the exact same thing. These are salts of compounds**
:16:50 **and they are highly pure and stable.**
:16:54 **In Column 1, the patentees go on a little**
:16:56 **further and they tell us about what was known. When they**
:16:59 **use the word known, they are talking about what went before.**
:17:03 **What they say is, from document PCT, the 212 document, novel**
:17:09 **derivatives of 3,3-diphenylpropylamines are known. If one**
:17:13 **looks at the WO publication of the PCT application, right at**
:17:20 **Page 11, we see a description that says, "Particularly**
:17:23 **preferred phenolic monoesters are," and fesoterodine is**
:17:27 **listed.**
:17:28 **Elsewhere in the patent, it says the compounds**
:17:30 **of the invention can be formed of free bases and their**
:17:35 **salts. Elsewhere in the patent -- I have not illustrated it**
:17:38 **on the slide -- is an actual production of the recorded**
:17:41 **synthesis of fesoterodine hydrochloride, which is a salt.**
:17:44 **The patentees say, this is known, and because it's known,**
:17:48 **it's not part of the '650 patent claims.**
:17:53 **The patentees go on in Column 1 and they say,**

:17:57 "Preferred are the known compounds according to Formula A substituted as shown."

:18:00 It then talks about the fact that the preferred known compounds, the 3,3-diphenylpropylamines and whatever else is disclosed in the PCT application, have certain disadvantages. For example, in Column 1, Lines 47 to 62, the patent tells us the known compounds have low water solubility. They have restricted oral bioavailability. The monoesters undergo intermolecular rearrangement, they degrade, they form diols, et cetera.

:18:35 The '650 patent then tells us that salts of the known compounds can be obtained but they can be amorphous or hygroscopic or too chemically unstable to form pharmaceutical compounds.

:18:48 Quite simply, because all of these compounds are known and they all have stated disadvantages, they are not part of the '650 patent claims.

:18:58 We then get to the bottom of Column 1 of the '650 patent, where the patent says, "Surprisingly, it has now been found that all these disadvantages can be avoided if the known compounds, general Formula A, are prepared under a special reaction process and then converted to a salt."

:19:20 The special reaction process is used to make compounds of general Formula A.

I think counsel referred to those as the free-base form but not the salted form. But there is nothing in the patent that says the special reaction process includes the last step, salt formation. And that is the reason defendants have not proposed salt formation as part of its claim construction, because the patent tells us that only making the intermediate general Formula A is made by the special process.

Moving along, following that disclosure of surprisingly, the '650 patent then tells us, and summarizes the three known compounds the claimed subject matter is intended to address, to provide highly pure crystalline compounds, to provide a method of manufacturing stable intermediates, and to provide a method of manufacturing in high-yield chemo- or regioselectivity.

Again, they tell us that problem is solved by providing the stable crystalline compounds of general Formula I.

If we compare just using the first two columns of the '650 patent, if we compare what is stated to be known and compare that to what is claimed, what we find is that 3,3-diphenylpropylamines were known both as neutral forms as well as salts with physiologically compatible acids. After all, fesoterodine and racemic fesoterodine are said to be known. They are in the PCT application.

What is claimed in the '650 patent are the 3,3-diphenylpropylamine compounds only as salts. The known compounds are said to be disadvantageous. The claimed compounds were said to be advantageous.

So there has to be a difference between what is being claimed and what the patentees tell us is already known. Of course, the patentees tell us exactly what the difference is between what is claimed and what went before it.

In Column 9, they say, "In order to obtain the compounds in accordance with the invention in the form their salts the special reaction process via intermediate stages and individually identifiable intermediate products is crucial."

First and foremost, this disclosure says compounds of the invention. That means all compounds of the invention. They are not talking about selective embodiments or certain subclasses of compounds. It is a general statement as to the compounds of the invention as a whole.

It's akin to statements such as, "The present invention is."

The statement then talks about the special reaction process via particular intermediate stages, et cetera. Special is a word chosen by the patentee. It means not conventional or routine, but not something left to the

knowledge of a person of ordinary skill, but something of greater significance.

The patentee talks about particular intermediate stages and individually identifiable compounds. That doesn't mean any intermediates which might be transient or not characterized. They are very particular about what the special reaction process is.

Of course, finally, of course, it has been much briefed and much spoken about, the use of the word crucial at the end of the sentence. Obviously, crucial is not a common word that is found in patents. We believe crucial conveys something to the reader that is critical and imperative, and in its use here suggests to defendants or should tell the person of ordinary skill in the art that the reaction process used to obtain the compounds of the invention are critical and imperative.

Now, the patentees could have said that the process and the particular intermediates used to make them were desirable or advantageous or beneficial. But they didn't say that. They could have said the process steps were preferred or highly preferred or more preferred. They didn't say that, either. They could have even said important, or fundamental. But they used the word crucial. And defendants submit that that language simply can't be ignored in deciding what compounds are within the scope of

:23:28 **the claims.**

:23:30 **We have talked a lot about the special reaction**
:23:33 **process. I would like to walk through that briefly.**

:23:44 **Figure 1 of the '650 patent illustrates the**
:23:48 **reaction steps by which the claimed salts are made.**
:23:52 **Beginning with the starting material, it is designated No. 3**
:23:56 **in Figure 1, Compound 3 has to be made and the '650 patent**
:24:01 **tells people how to make it.**

:24:03 **Beginning with Compound 3, Figure 1 shows us how**
:24:06 **to get to Compound 6, which is an intermediate en route to**
:24:11 **the claimed salts. And Figure 1 tells us you can take one**
:24:14 **of two pathways. You can either begin with Compound 3, and**
:24:18 **reduce first and then hydrogenate, or you can carry out**
:24:21 **those steps in the reverse order, you can hydrogenate and**
:24:25 **then reduce. Either way, one obtains Compound 6 as a result**
:24:31 **of the reaction process.**

:24:35 **After one obtains Compound 6, necessary to all**
:24:40 **of the productions or syntheses disclosed in the patent is**
:24:44 **an acylation step followed by salt formation.**

:24:49 **The patent tells us that the first three of**
:24:51 **these steps are crucial -- again, this is from the bottom of**
:24:56 **Column 1 -- but that the fourth step, salt formation, is not**
:25:01 **crucial. It is telling that every one of the examples in**
:25:03 **the '650 patent follows this special reaction pathway in**
:25:07 **Figure 1. I think it's equally telling that there is no**

:25:11 **disclosure in the patent of any other ways to make the**
:25:14 **compounds of general Formula A.**
:25:18 **So much for the patent disclosure.**
:25:20 **The prosecution history, admittedly, there was**
:25:22 **not much. There was a single office action. It was**
:25:26 **responded to, and the patent was allowed.**
:25:28 **Interestingly, after the patent was issued, the**
:25:30 **patentees filed a certificate of correction to the language**
:25:33 **of the patent. The original language of the patent stated**
:25:36 **that "Compounds of general Formula I are that," and A, B, C,**
:25:43 **D were the four reaction steps used to make them. They**
:25:48 **corrected that language to say, "Compounds of general**
:25:51 **Formula I are manufactured in that," and then the four**
:25:54 **reaction steps followed.**
:25:56 **Interestingly, the patentee doesn't say those**
:26:00 **four steps, the compounds are preferably manufactured or**
:26:03 **typically manufactured. They said in the certificate of**
:26:07 **correction: They are manufactured in the four process**
:26:11 **steps.**
:26:13 **On this record, Your Honor, both the patent**
:26:17 **language and the language of the prosecution history, we**
:26:19 **submit it is hard to imagine a clearer case for construing**
:26:22 **Claim 1 as encompassing only those compounds that are made**
:26:31 **by the crucial reaction process of the selected**
:26:33 **intermediates.**

:26:34 **But that is what the patent tells us. That's**
:26:37 **what the patent said. And that is how defendants submit**
:26:41 **Claim 1 should be construed.**
:26:42 **I would like to address just a couple of**
:26:44 **comments made by plaintiffs in their briefs.**
:26:48 **Plaintiffs said that we completely misread**
:26:51 **disclosure. They told the Court that the word crucial bears**
:26:55 **no connection to the claimed compounds. They further**
:26:58 **explain that crucial and special relate to the methods of**
:27:04 **manufacturing as a separate group of claimed inventions.**
:27:07 **But they are beside the point as to the product claims.**
:27:10 **With respect, Your Honor, we submit their**
:27:13 **arguments are without merit. Quite simply, if one reads the**
:27:17 **disclosure of Column 9, it says, "In order to obtain the**
:27:20 **compounds in accordance with the invention, the special**
:27:23 **reaction process is crucial."**
:27:25 **That passage doesn't say, In order to perform**
:27:28 **the method of manufacturing of the invention, the special**
:27:32 **process steps are crucial.**
:27:33 **It says, "The process is crucial for obtaining**
:27:36 **the claimed compounds."**
:27:37 **And so we submit that "crucial" absolutely is a**
:27:41 **description of the process steps required to make the**
:27:44 **compounds.**
:27:46 **I understand plaintiffs don't like the word**

crucial in this patent. But I think it's incorrect for them to say it bears no relation to the compounds that are claimed in Claim 1.

A second argument plaintiffs have made is that the reaction process of the '650 patent is a preferred embodiment, not necessary, it's preferred, and it doesn't limit the claims. But the patentees, in the actual specification, don't call the reaction process preferred, Your Honor. They call it crucial.

The patentees certainly knew the difference between the two words, because they used preferred to describe compounds of intermediates, but never in connection with any process steps. The plaintiffs don't cite to anything in the language of the patent downgrading the crucial nature of the process steps to one that is only preferred, because preferred is never used in connection with the process.

Next, plaintiffs talk about the fact that defendants are trying to convert Claim 1 into a product-by-process claim. And it's our position that we are not, Your Honor. On its face, Claim 1 is a product claim. Plaintiffs say there is no process steps limiting the language in Claim 1 on its face. And we agree.

They say that none of the language typically signaling a process claim -- or a product-by-process claim

:29:14 **appears in Claim 1. And we agree with that as well.**

:29:17 **It is our position that Claim 1 is a product**

:29:20 **claim whose literal scope is narrower than the words of the**

:29:25 **claim would otherwise suggest based on the language in the**

:29:29 **specification, basic lexicography, where the patentee tells**

:29:33 **us what we have to do to get the compounds of Claim 1.**

:29:37 **But that doesn't make Claim 1 a**

:29:40 **product-by-process claim. As the plaintiffs have pointed**

:29:44 **out, product-by-process claims are typically reserved for**

:29:48 **those products that can't be described or otherwise claimed**

:29:51 **other than by which the method they were made. That is not**

:29:54 **the position we are taking here.**

:29:57 **In product-by-process claims, the products**

:30:01 **themselves are novel. We don't concede that the products of**

:30:04 **Claim 1 are novel.**

:30:07 **In product-by-process claims, the process**

:30:11 **limitations serve as limitations for purposes of**

:30:16 **infringement but not validity. Again, we are not arguing**

:30:18 **any of that. We are not taking that position.**

:30:21 **What they rely on for saying that the process of**

:30:25 **the '650 patent is non-restrictive is a disclosure that they**

:30:29 **showed Your Honor a little bit earlier in Column 9.**

:30:37 **Referring to Figure 1, we have our language talking about**

:30:41 **the crucial reaction process. In the next paragraph, Column**

:30:46 **9, it says, This is explained using reaction diagram Figure**

:30:49 1 **1 in which conversions with R-configured compounds are**
:30:54 2 **described but without this being restrictive.**
:30:57 3 **We submit that that last portion of not being**
:31:02 4 **restrictive, Your Honor, it's not a statement that the**
:31:04 5 **process steps can be varied. It's a statement that that**
:31:08 6 **process shown in Figure 1 isn't limited to the R-configured**
:31:13 7 **compounds that are shown. If we look at Figure 1, they are**
:31:16 8 **all isomeric. They all show R-configured compounds. And as**
:31:20 9 **proof of this point, we have only to look at Claim 1. Claim**
:31:24 10 **1 is not directed solely to the R-plus compounds. It is**
:31:27 11 **directly to the R and the S and the racemic.**
:31:31 12 **We submit that this statement is no more than**
:31:34 13 **perhaps supporting disclosure for the breadth of Claim 1**
:31:37 14 **which includes R, S, and racemic. But we don't read this**
:31:41 15 **statement as saying these process steps can be varied.**
:31:48 16 **Plaintiffs also make some arguments about claim**
:31:50 17 **differentiation, Your Honor. And they say that in their**
:31:53 18 **opening brief at Page 11 and 12. They, of course, say, if**
:31:58 19 **the Court adopts defendants' proposed construction, the**
:32:02 20 **doctrine of claim differentiation would be frustrated or**
:32:06 21 **violated. We have Claim 1 and 7 covering the same material.**
:32:10 22 **We absolutely disagree, for a couple of reasons.**
:32:13 23 **First, the only process limitations, the only**
:32:16 24 **process features defendants believe are part of Claim 1 are**
:32:19 25 **Steps 1 through 3.**

:32:21 **The fourth step, salt formation, is not part of**
:32:26 **defendants' construction. To be clear, the salt formation**
:32:28 **step is part of Claim 7. So even if Your Honor were to**
:32:32 **adopt defendants' construction, Claims 1 and 7 would at**
:32:34 **least be different by recitation in Claim 7 of the salt**
:32:38 **formation step.**
:32:41 **Second, in defendants' proposed construction, as**
:32:44 **was shown in the figure, the first two steps can be carried**
:32:47 **out in either order. Hydrogenation first, then followed by**
:32:52 **reduction, or in reverse. In contrast, Claim 7 always**
:32:56 **requires that the hydrogenation step occur first and**
:32:59 **reduction second, not in the reverse order.**
:33:02 **Again, a second reason why, even if Your Honor**
:33:06 **adopts defendants' construction, Claims 1 and 7 will always**
:33:09 **be differentiated.**
:33:14 **A final point I would like to address, Your**
:33:17 **Honor, the plaintiffs say that defendants' proposed**
:33:20 **construction is nonsensical and inconsistent because we**
:33:26 **omitted the fourth step from our proposed construction, we**
:33:28 **omitted the salt formation step. But in making that**
:33:31 **argument, plaintiffs concede in their opening brief that all**
:33:35 **four Steps A through D are necessary to obtain the claimed**
:33:41 **compounds in the salt form.**
:33:42 **To be clear, defendants agree that all four**
:33:44 **steps are necessary. But we only propose the first three as**

:33:51 **limitations affecting the compounds of Claim 1 because**
:33:54 **that's what the patentee tells us. He doesn't tell us that**
:33:57 **Step 4, the salt formation step, is special or couldn't be**
:34:02 **left to the knowledgeable person of ordinary skill in the**
:34:04 **art.**

:34:05 **We submit that our proposed construction is not**
:34:08 **incomplete because we omitted that fourth step. Process**
:34:12 **claims, product-by-process claims, aren't required to recite**
:34:16 **every step in a process. In a multi-step process less than**
:34:20 **all of the steps can be claimed. That is fairly well known.**

:34:23 **I would point out, I believe there is an**
:34:25 **inconsistency with plaintiffs saying that the four specific**
:34:30 **steps, A through D, are necessary to obtain the compounds in**
:34:35 **the salt form. But elsewhere they say that the four**
:34:40 **specific steps are only exemplary. They are preferred. And**
:34:44 **that they are non-restrictive. They don't limit the claims.**
:34:48 **I am not sure how those two approaches are consistent.**

:34:53 **But I guess I would close by saying that on this**
:34:56 **record, Your Honor, given the language of the patent and the**
:34:59 **prosecution history, and the plaintiffs' recognition that**
:35:02 **the four steps are necessary, it is clear that the claimed**
:35:06 **compounds are differentiated by those that were known in**
:35:09 **Column 1, 3,3-diphenyldiphenylproplyamines, only based on**
:35:14 **the reaction process used to make them.**

:35:16 **As plaintiffs have said, there is nothing in the**

:35:18 **claims that talk about stability or crystallinity or**
:35:21 **anything else. So the process steps are really the only**
:35:25 **difference.**
:35:26 **That's all I have, Your Honor.**
:35:28 **THE COURT: Okay. Thank you, counsel.**
:35:33 **Plaintiff, brief reply.**
:35:35 **MR. TRAINOR: Very briefly, Your Honor.**
:35:40 **I am not sure that any of what we pointed out in**
:35:43 **our argument was actually responded to there.**
:35:47 **What I think was most telling is, we went**
:35:49 **through a whole lot of description on the specification of**
:35:54 **not this patent but primarily of other documents. And one**
:35:57 **thing we didn't see was the words of the claim. We didn't**
:35:59 **see Claim 1 up there, which is where you start with claim**
:36:02 **construction. That is black-letter patent law.**
:36:05 **With respect to the argument of claim**
:36:08 **differentiation, and it sort of ties into a point that we**
:36:11 **made in our opening, I think we are all in agreement that**
:36:14 **all four steps are required to make a salt. And the**
:36:17 **defendants are suggesting our construction leaves out that**
:36:21 **fourth step. I didn't understand that when we read the**
:36:24 **briefs. I don't understand it now.**
:36:26 **Claim 1 is to a salt. Claim 1, we put it on the**
:36:31 **screen, is to a compound in a salt form.**
:36:35 **To take the position that we agree, you need to**

:36:38 **have all four steps to make a salt, and in the proposed**
:36:42 **construction it leaves off the salt formation step, you are**
:36:45 **necessarily left with a claim that had issued and was**
:36:48 **directed to a salt as issued from the Patent Office but**
:36:50 **under this construction is no longer a salt. And that**
:36:53 **cannot be the proper construction.**
:36:55 **The other thing I would just point out, Your**
:36:57 **Honor, we heard a lot about what is known and this was known**
:37:00 **and that was known. 3,3-diphenylpropylamines, of course,**
:37:04 **they were known. As a class of compounds, they have been**
:37:06 **known since the beginning of the 20th century, if not**
:37:09 **earlier.**
:37:10 **The few references to the more specific genus of**
:37:15 **the monoesters being known, that is a reference to the**
:37:17 **inventors' own co-pending application. It was not known in**
:37:20 **the prior art. It is not prior art. We have heard no**
:37:22 **argument as to why we are incorrect that that document in**
:37:26 **any disclosure about these salts, any disclosure about the**
:37:30 **processes, is prior art.**
:37:31 **In fact, when you really think about that**
:37:33 **argument, and we hear about these properties and these are**
:37:35 **the problems with tolterodine and these are the problems**
:37:39 **with the 5-HMT, all of that sort of smacks of an argument on**
:37:42 **the merits of invalidity, that this claim should not have**
:37:46 **issued because these things were not known about the**

compounds.

That is not an issue for claim construction. The question is whether there is sufficient structure in this claim that should be left as is and would be understood by a person of ordinary skill in the art.

Thank you, Your Honor.

THE COURT: Thank you.

Hold on just a second.

(Pause.)

All right. Counsel, is there anything we should discuss while we have you all here? Is everything going along smoothly? Do we need to address anything while we are together?

Wonderful. Safe travels.

(Hearing concluded at 10:37 a.m.)

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Reporter: Kevin Maurer